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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/553,969 04/21/00 WALLACE

D 17067 002010

EXAMINER

020350 HM22/1201  
TOWNSEND AND TOWNSEND AND CREW  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO CA 94111-3834

ART UNIT ARE T PAPER NUMBER

DATE MAILED: 15

12/01/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/553,969

Applicant(s)

WALLACE ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 9-22-00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

**DETAILED ACTION**

Receipt of preliminary amendment filed 4-21-00 and information disclosure statement filed 9-22-00 is acknowledged. Claims 2-18 have been canceled as requested. Claim 1 is pending.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al (5,023,082; hereafter '082).

'082 discloses implants comprising hydrolyzed (fragmented) gelatin that are substantially free of an aqueous phase (C 5, L 10-20; C 8, L 48-62; examples). Page 8, lines 7-17 define the term "substantially free of an aqueous phase" as meaning that the compositions will be fully or partially hydrated, but will not be hydrated above their capacity to absorb water. C 8, L 48-62 discloses that after drying of the composition, the composition will have from 7.5% to about 17.5 % solvent, 3.8 % to about 21 % plasticizer and from about 4% to about 24% of pharmaceutical agent. '082 also states that the pharmaceutical agent may be absorbed into the implant (C 9, L 14-22). Accordingly, '082 discloses that the implants are able to absorb an active agent and that after drying the compositions have as little as 15.3% aqueous phase.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al (5,023,082; hereafter '082).

5. '082 teaches implants comprising hydrolyzed (fragmented) gelatin that are substantially free of an aqueous phase (C 5, L 10-20; C 8, L 48-62; examples). Page 8, lines 7-17 define the term "substantially free of an aqueous phase" as meaning that the compositions will be fully or partially hydrated, but will not be hydrated above their capacity to absorb water. C 8, L 48-62 discloses that after drying of the composition, the composition will have from 7.5% to about 17.5 % solvent, 3.8 % to about 21 % plasticizer and from about 4% to about 24% of pharmaceutical agent. '082 also states that the pharmaceutical agent may be absorbed into the implant (C 9, L 14-22). Accordingly, '082 teaches that the implants are able to absorb an active agent and that after drying the compositions have as little as 15.3% aqueous phase. '082 also teaches manipulation of the amount of solvent, plasticizer, and pharmaceutical agent according to desired flexibility of the implant. Accordingly, it would be obvious to adjust the amounts of these components with the expectation that the implants would become accordingly more or less flexible. Such a formulation would be "substantially free of an aqueous phase."

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,066,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and 6,066,325 claim a genus and a species and are therefore obvious over each other.

8. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,063,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a genus and 6,063,061 claims a method that discloses a species and are therefore obvious over each other.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 6 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) for regular communications and (703) for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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November 29, 2000